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(12) **United States Patent**
Tu et al.(10) **Patent No.:** **US 9,844,545 B2**(45) **Date of Patent:** ***Dec. 19, 2017**(54) **METHYLPHENIDATE EXTENDED RELEASE CHEWABLE TABLET**(71) Applicant: **Tris Pharma, Inc.**, Monmouth Junction, NJ (US)(72) Inventors: **Yu-Hsing Tu**, West Windsor, NJ (US); **Ashok Perumal**, Monmouth Junction, NJ (US); **Kalyan Kathala**, Monmouth Junction, NJ (US)(73) Assignee: **TRIS PHARMA, INC.**, Monmouth Junction, NJ (US)

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(63) Continuation of application No. 15/009,480, filed on Jan. 28, 2016, which is a continuation of application No. 14/872,226, filed on Oct. 1, 2015, now Pat. No. 9,295,642, which is a continuation of application No. 14/624,998, filed on Feb. 18, 2015, now Pat. No. 9,180,100, which is a continuation of application No. 14/300,580, filed on Jun. 10, 2015, now Pat. No. 8,999,386, which is a continuation of application No. PCT/US2013/054930, filed on Aug. 14, 2013, application No. 15/491,547, filed on Apr. 19, 2017, which is a continuation of application No. 15/009,468, filed on Jan. 28, 2016, which is a continuation of application No. 14/872,226, filed on Oct. 1, 2015, now Pat. No. 9,295,642, which is a continuation of application No. 14/624,998, filed on Feb. 18, 2015, now Pat. No. 9,180,100, which is a continuation of application No. 14/300,580, filed on Jun. 10, 2014, now Pat. No. 8,999,386, which is a continuation of application No. PCT/US2013/054930, filed on Aug. 14, 2013.

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A61K 9/28 (2006.01)(52) **U.S. Cl.**CPC **A61K 31/4458** (2013.01); **A61K 9/0056** (2013.01); **A61K 9/20** (2013.01); **A61K 9/209**(2013.01); **A61K 9/2013** (2013.01); **A61K 9/28** (2013.01); **A61K 47/48176** (2013.01)(58) **Field of Classification Search**CPC **A61K 9/20**; **A61K 9/2004**; **A61K 9/2072**; **A61K 9/2077**

See application file for complete search history.

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Primary Examiner — Micah Paul Young(74) *Attorney, Agent, or Firm* — Howson & Howson LLP; Cathy A. Kodroff; Egon Berg(57) **ABSTRACT**

An oral methylphenidate extended release tablet is described, which can be scored and still retain its extended release profile. The tablet contains a combination of an uncoated methylphenidate-ion exchange resin complex, a barrier coated methylphenidate-ion exchange resin complex-matrix, and an uncomplexed methylphenidate active component. Following administration of a single dose of the extended release methylphenidate chewable tablet, a therapeutically effective amount of methylphenidate is reached in less than about 20 minutes and the composition provides a twelve-hour extended release profile.

30 Claims, 1 Drawing Sheet